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November 27, 2019

VIA E-MAIL

Adam M. Slater, Esquire
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068

Re: In re Valsartan NDMA Products Liability Litigation Case
No. 1:19-md-02875-RBK-JS: Custodians

Dear Adam:

This letter is in response to the parties' November 25, 2019 meet and confer regarding custodians. As you know, Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") initially proposed seven custodians on September 3, 2019; added three on October 7; and added 13 on October 16, for a total of 23 ZHP custodians. In addition, on October 22, Prinston Pharmaceutical Inc. ("Prinston") and Solco Healthcare U.S., LLC ("Solco") proposed five custodians—including three of the 17 that Plaintiffs proposed on October 8, 2019—bringing the total to 28 proposed custodians for the ZHP Defendants.¹

As we noted on the Monday meet and confer, these custodians were proposed in response to Plaintiffs' October 3, 2019 letter requesting that the ZHP Defendants identify certain people most knowledgeable about or involved in certain areas (e.g., employees with "primary responsibility to assess the contamination issue, whether from a testing, regulatory, investigation, [or] marketing standpoint," "employees who were involved in and made the decisions with regard to the manufacturing process," "employees who would be most knowledgeable regarding testing," "employees and/or other persons/entities who were responsible for investigating and determining

¹ "ZHP Defendants" refers to ZHP, Prinston, Solco, and Huahai U.S., Inc., the four entities that have been named as defendants in the above-captioned matter.

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the root cause or causes of the contamination,” and “[w]ith regard to finished dose manufacturing, and distributors,” the employees “responsible for or involved in testing the API”). The ZHP Defendants have proposed custodians that are responsive to all of these areas, plus more, and were identified by counsel through review of core discovery productions and through interviews with the heads of the relevant departments. Furthermore, Plaintiffs had the opportunity to ask a corporate representative, Mr. Jun Du, extensive questions about these topics and to assure themselves that the ZHP Defendants’ custodian list was adequate in a Court-ordered in-person meeting that spanned 5 hours on October 23, 2019. Mr. Du answered every question asked of him regarding the ZHP Defendants to the best of his ability and current knowledge.

In a series of letters since November 12, Plaintiffs have now proposed that the list be increased from 28 to **159** custodians. Plaintiffs started by proposing 141 custodians. On November 14, we responded with a letter explaining why that list was facially unreasonable under applicable law. Plaintiffs declined to substantively respond to that letter, and instead responded on November 22 by removing 22 of their proposed custodians while simultaneously proposing an additional 32, for a total of 151. On November 25, just two days ago, Plaintiffs circulated a list adding another 8, for a total of 159. During our meet and confer on Monday, Plaintiffs refused to discuss their rationales for removing and adding custodians in this fashion and refused to respond to the points we raised in our November 14 letter. In fact, when asked, Plaintiffs stated they would not be providing any explanation for why they believe the ZHP Defendants’ proposed 28 custodians are inadequate, or why they believe any of the 127 newly added individuals are appropriate custodians. Plaintiffs’ list of proposed custodians is facially unreasonable, and the refusal to discuss the reasoning behind this list has frustrated and slowed this process.

In addition, Plaintiffs resort to demanding additional custodians for no stated reason other than they appear to list a ZHP company as their employer on LinkedIn or are mentioned on a ZHP company website, without any regard to whether they have any involvement whatsoever with valsartan (let alone whether they would have relevant and non-duplicative documents). This position is not reasonable. Without providing any basis to believe that Plaintiffs’ 127 additional proposed custodians are meaningfully involved with valsartan, it is not reasonable to demand that the ZHP Defendants undertake the burden, expense, and time of reviewing each of Plaintiffs’ proposals to understand all the details of their employment and hypothetical involvement with valsartan. This is especially true given that Plaintiffs could have provided their proposals, which were pulled from the internet, months ago. Instead, the vast majority of the total custodians now proposed were not mentioned by Plaintiffs in any of the correspondence, meet and confers, or meeting with Mr. Du, but were instead raised for the first time either on November 12 or November 22, even though the Court has been clear that December 11 is the date on which the ESI custodian lists would be resolved.

Notwithstanding that the 28 custodians ZHP has proposed were suggested based on thorough investigation, I suggested during our meet and confer that the parties agree to a total of 50 custodians. Plaintiffs declined to agree to this proposal, but stated that they would “definitely seriously consider” it. In a showing of good faith and with the hope that the parties can ultimately

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agree to such a list without Court intervention, below please find the ZHP Defendants' preliminary review of the custodians on Plaintiffs' November 25 list. Because ***Plaintiffs have added 40 custodians since Friday, November 22***, the ZHP Defendants have not had sufficient time to investigate all 127 newly added individuals, although that investigation continues. By providing Plaintiffs with the lists below, the ZHP Defendants are in no way conceding or implying that any undiscussed individuals are appropriate, acceptable, or agreed upon (other than the 28 already proffered).²

I. Plaintiffs' Proposed Custodians Listed More than Once³

As mentioned in Monday's meet and confer, Plaintiffs list certain individuals multiple times.

1. Chaojun Zie (#3) is the same as Chaojun Xie (#36). The correct spelling is Chaojun Xie.
2. Dachuan Zhao (#7) is the same as Dachuan Zhao (#143).
3. Yun Jin (#15) is the same as Yun Jin (#44).
4. Wei Cheng (#16) is the same as Wei Chen (#94) and Wei Chang (#118). The correct spelling is Wei Cheng.
5. Cunxiao Ye (#26) is the same as Jenson Ye (#58).
6. Quang Zhou (#37) is the same as Qiang Zhou (#49). The correct spelling is Qiang Zhou.

² This letter is based on information compiled by counsel and reflects counsel's current understanding of the roles of various employees. It does not contain any statements or representation by the ZHP Defendants or any of their employees, and may not be construed as such. The letter is provided as part of the parties' informal, good-faith efforts to exchange information to help identify ESI custodians and should not be considered binding in any way. Further, this letter is not, and should not be considered in any manner, a waiver of the ZHP Defendants' rights, privileges, or defenses, jurisdictional or otherwise, or of their rights to object to the discoverability or admissibility of any information disclosed.

³ As a courtesy, we have added numbers to Plaintiffs' list for ease of reference. Custodian numbers correspond to Plaintiffs' Preliminary List of Custodians for ZHP and Its Subsidiaries as of 11/25/2019. In addition, we have made our best efforts to refer to individuals using the individual's given name followed by family name.

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7. Ying Xiong (#38) is the same as Ying Xiong (#98).
8. Xiamong Liu (#66) is the same as Xiaoming Liu (#79). The correct spelling is Xiaoming Liu.
9. Eric Wen-Chien Tsai (#80) is the same as Wenjian Cai (#142).
10. Li Tan (#146) is the same as Lily Tan (#152).
11. Yula Wang (#155) is the same as Luke Wang, whom Plaintiffs withdrew on November 22. The correct spelling of the Chinese name is Yulu Wang.

II. ZHP'S API Quality Assurance Department

A. Current Custodians

1. Jucai Ge (#19). Jucai Ge is currently the Director of API Quality Assurance at the Chuannan facility. In that role, she oversees QA for all API manufactured at Chuannan, including valsartan API. She reviews and approves cGMP procedures, and she also oversaw the root cause investigation into the nitrosamine impurities. She has worked for ZHP since 2000.
2. Yuelin Hu (#20). Yuelin Hu is the Assistant Director who oversees Production QA Department 1, which includes oversight of valsartan. Yuelin Hu has worked for ZHP since 2005. She was a member of the committee that considered the manufacturing process change implemented in December 2013. She is involved in review of deviations and out-of-specification testing for valsartan, and reviewed and approved the deviation investigation reports related to the nitrosamine impurities.
3. Wei Cheng (#16). Wei Cheng is a Senior Manager within the Corporate Quality Assurance division. He has worked for ZHP since 2013. As an English-speaker, Wei Cheng has acted as a translator and communicated with customers and regulatory authorities, including about the nitrosamine impurities and related recalls.

B. Custodians ZHP Agrees to Add

4. Baozhen (Jennifer) Chen (#25). Baozhen Chen is currently an Assistant Director who oversees the Corporate Quality Assurance division within API Quality Assurance. She has worked for ZHP since 2001. She is responsible for reviewing and approving cGMP-related procedures and was involved in the valsartan recall. She is also involved in overseeing qualification of

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vendors, including sources of raw materials. As Plaintiffs note, Ms. Chen also attended the closeout meeting during the FDA's 2017 inspection of the Chuannan facility.

5. Dongqin Wang (#28). Dongqin Wang is currently the Assistant Director who oversees the Quality Compliance Department within API Quality Assurance. Dongqin Wang reviews and approves certain quality documents like SOPs, reports, and investigations, including for valsartan. Dongqin Wang has worked for ZHP since 2016 and participated in the root cause analysis for the nitrosamine impurities. As Plaintiffs note, Dongqin Wang also attended the closeout meeting during the FDA's 2017 inspection of the Chuannan facility.

C. Proposed Custodians that ZHP Opposes as Cumulative or Not Materially Involved with Valsartan

6. Cunxiao (Jenson) Ye (#26). Cunxiao Ye is the former VP of API Quality Assurance at the Chuannan facility. He worked for ZHP from 2010 to 2018. Because he was a high-ranking executive within ZHP, Cunxiao Ye did not have as close involvement with oversight of valsartan as the above proposed custodians, who reported up to him.
7. Shang Fei (#43). Shang Fei is the current VP of API Quality Assurance at the Chuannan Facility. She was hired in January 2019 to fill Cunxiao Ye's position. Because of her short tenure at ZHP and her high-level position, she is less involved with the details of valsartan QA and the nitrosamine impurities than the above agreed custodians. In addition, both Jucai Ge and Baozhen Chen report directly to Shang Fei. Whatever information she has related to these actions is therefore likely cumulative to the information held by existing custodians. Although Shang Fei reviewed and approved of the deviation investigation report related to the TEA process, other existing custodians—namely, Jucai Ge, Yuelin Hu, Peng Dong, and Qiangming Li—also reviewed and approved several versions of that report.
8. Xiaohong Zhao (#22). Xiaohong Zhao is currently a Director within the API Quality Assurance department at the Chuannan facility. She was transferred into that position in February 2019. Before that time, she had no involvement with valsartan. In her current role, Xiaohong Zhao reports directly to Jucai Ge and directly supervises Yuelin Hu, two existing custodians. Xiaohong Zhao therefore has less information related to valsartan and, to the extent she has such information, it will be cumulative of Yuelin Hu and Jucai Ge's.

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9. Caifeng Zhao (#27). Caifeng Zhao is a Manager of Production QA Department 1. She reports to Yuelin Hu, who reports to Jucai Ge, two existing custodians. She is therefore cumulative to those two custodians. In addition, although Caifeng Zhao drafted the deviation investigation report related to the TEA process, other existing custodians—namely, Jucai Ge, Yuelin Hu, Peng Dong, and Qiangming Li—reviewed and approved of several versions of that report.
10. Y.F. Chen (#30). Y.F. Chen is a Senior Supervisor in API Quality Assurance who has worked for ZHP since 2017. (S)he reports to Dongqin Wang, an existing custodian with superior knowledge of the applicable SOPs and the root cause investigation. As Plaintiffs' spreadsheet indicates, Y.F. Chen reviewed the validation reports for the lc/ms method for Losartan Potassium and Irbesartan, but not the gc/ms method for valsartan.

III. ZHP's API Quality Research Department

A. Current Custodians

1. Min Li (#4). Min Li is currently the VP of Analytical Operations at ZHP. He oversees the API Quality Research and API Quality Control departments. In that role, he oversees the research of analytical methods, including for valsartan generally and for the nitrosamine impurity specifically. He has worked for ZHP since 2014.
2. Wenquan Zhu (#55). Wenquan Zhu is currently the Director of API Quality Research. He reports to Min Li and has worked for ZHP since 2006. He is responsible for research of analytical methods, including for valsartan and for the nitrosamine impurity specifically.

B. Custodians ZHP Agrees to Add

3. Wenbin Chen (#52). Wenbin Chen has worked for ZHP since November 2013. Before May 2019, Wenbin Chen was the Technical Director of the Key Lab within API Quality Research. The Key Lab was primarily responsible for analytical research and testing of pilot products. In May 2019, ZHP reorganized the API Quality Research department and transferred the Key Lab to a new department called the Center for Excellence in Modern Analytical Technology (CEMAT). Wenbin Chen is currently a Director within that group. Wenbin Chen was involved in the development of the gas chromatography/mass spectrometry method that ZHP developed to identify nitrosamines.

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C. Proposed Custodians that ZHP Opposes as Cumulative or Not Materially Involved in Valsartan

4. Qiang Zhuo (#49), Tong Wu (#50), and Tan Xiao (#51). These three employees report to Wenbin Chen, who reports to Wenquan Zhu, who in turn reports to Min Li. They are therefore duplicative of the above custodians and will have cumulative information. To the extent that Qiang Zhou, Tong Wu, and Tan Xiao contributed to the validation report for the gc/ms method for detection of nitrosamines, Wenbin Chen oversaw the development of that method and also reviewed and signed off on that report.

IV. ZHP'S API Quality Control Department

A. Current Custodians

1. Min Li (#4). Min Li is currently the VP of Analytical Operations at ZHP. He oversees the API Quality Research and API Quality Control departments. In that role, he oversees the research of analytical methods, including for valsartan generally and for the nitrosamine impurity specifically. He has worked for ZHP since 2014.
2. Qiangming Li (#35). Qiangming Li is currently the Director of API Quality Control. He reports to Min Li and has worked for ZHP since 2011. He is involved in validations for valsartan testing and oversees the analytical lab where valsartan testing occurs, including chromatography and testing of solvents and other raw materials.

B. Proposed Custodians that ZHP Opposes as Cumulative or Not Materially Involved with Valsartan

3. Hongliang Wang (#23). Hongliang Wang is a former Team Leader within API Quality Control. (S)he reported to Qiangming Li, an existing custodian. (S)he left ZHP in 2012, only a few years into the relevant time period and before any valsartan API was manufactured for use in the United States market. Plaintiffs cite the valsartan assay method validation report as a reason for including Hongliang Wang, but Jucai Ge, an existing custodian, also reviewed and approved of that report.
4. Zhen Ye (#24). Zhen Ye is a former Team Leader within API Quality Control. (S)he reported to Qiangming Li, an existing custodian. (S)he left ZHP in 2013, only a few years into the relevant time period and before any valsartan API was manufactured for use in the United States market. Plaintiffs cite the valsartan assay method validation report as a reason for

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including Zhen Ye, but Jucai Ge, an existing custodian, also reviewed and approved of that report.

5. Chaojun Xie (#31), Guangping Hu (#32), and Huang Rui (#33). These are a former Analyst, Supervisor, and Manager, respectively, that used to work within ZHP's API Quality Control department. Chaojun Xie left ZHP in 2014; Guangping Hu left in 2015; and Huang Rui left in January 2011, all before or shortly after any valsartan API was manufactured for use in the United States market.

V. ZHP's Chuannan API Production Department

A. Current Custodians

1. Peng Wang (#70). Peng Wang is currently the Deputy General Manager of API Production at the Chuannan facility. He oversees API manufacturing at that facility, including the manufacture of valsartan API, and has worked for ZHP since 2004.

B. Custodians ZHP Agrees to Add

2. Wei Chen (#77). Wei Chen is currently the Deputy Director of API Production Department 1 at the Chuannan facility. He oversees the production workshops located within Department 1, which includes workshops that manufacture valsartan API, and reports to Peng Wang. He has been employed by ZHP since 2005. He also reviewed and approved the Deviation Investigation Report for the TEA Process.
3. Wenling Zhang (#73). Wenling Zhang is currently the Deputy Director of API Production Department 2 at the Chuannan facility. (S)he oversees the production workshops located within Department 2, which includes workshops that manufacture valsartan API, and reports to Peng Wang. (S)he has been employed by ZHP since 2008. (S)he also attended the closeout meeting for the May 2017 Chuannan inspection.

C. Proposed Custodians that ZHP Opposes as Cumulative or Not Materially Involved with Valsartan

4. Yanhua Meng (#87). Yanhua Meng is currently the General Manager of all of Chuannan; is duplicative of Wang Peng, Chen Wei, and Zhang Wenling; and as a high-ranking official, she has less detailed knowledge of the valsartan manufacturing process than the three proposed custodians in this department.

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5. Yongjun Jin (#68). Jin Yongjun formerly worked at Chuannan, but left ZHP in July 2012. (S)he recently returned to ZHP in August 2019 to work at the Xunqiao facility. Based on his/her limited employment at Chuannan during the relevant time period, Yongjun Jin is duplicative of Peng Wang, Wei Chen, and Wenling Zhang, all of whom have worked in Chuannan Production throughout the entire relevant period.
6. Jianzhong Yu (#72). Jianzong Yu is a former Director of Chuannan. (S)he left ZHP in April 2013. Based on his/her limited employment with ZHP during the relevant time period, Jianzhong Yu is duplicative of Peng Wang, Wei Chen, and Wenling Zhang, all of whom have worked in Chuannan Production throughout the entire relevant period.
7. Lijin Jiang (#74). Lijin Jiang is a former Director of Chuannan East Zone.⁴ (S)he was employed by ZHP from March 2015 to February 2018. Based on his/her limited employment with ZHP during the relevant time period, Lijin Jiang is duplicative of Peng Wang, Wei Chen, and Wenling Zhang, all of whom have worked in Chuannan Production throughout the entire relevant period. To the extent the justification for the custodian is that (s)he attended the closeout meeting for the May 2017 Chuannan inspection, ZHP currently proposes 11 of the 18 attendees as custodians. Including Lijin Jiang on that basis is therefore also cumulative.
8. Junhui Zuo (#76). Junhui Zuo is a former Deputy Plant Director who oversaw Engineering and Maintenance at Chuannan West Zone from August 2015 to November 2017. This person was employed by ZHP only for a short period and reported to Peng Wang, who is already a proposed custodian. To the extent the justification for this custodian is that they attended the closeout meeting for the May 2017 Chuannan inspection, ZHP currently proposes 11 of the 18 attendees as custodians. Including Junhui Zuo on that basis is therefore also cumulative.
9. Zhengjun Jia (#75). Zhengjun Jia is currently the Deputy Plant Director responsible for Engineering and Maintenance at the Chuannan facility, which includes overseeing the engineering equipment. (S)he has only been employed with ZHP since 2016. To the extent the justification for this custodian is that (s)he attended the closeout meeting for the May 2017 Chuannan inspection, ZHP currently proposes 11 of the 18 attendees as

⁴ Chuannan East Zone and Chuannan West Zone were recently reorganized into Chuannan Production Department 1 and Chuannan Production Department 2.

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custodians. Including Zhengjun Jia on that basis is therefore also cumulative.

10. Youhu Wang (#71). Plaintiffs' chart incorrectly refers to Youhu Wang as "Technology leader." This employee is the Deputy Director of Production and Operation Department, which oversees the warehouse and internal order management. This employee reports to Peng Wang and is unlikely to have non-cumulative information related to the core issues in this case.
11. Congsheng Jin (#67). Congsheng Jin is a former manager within the Chuannan facility. (S)he left ZHP's employment several years before 2010.

VI. ZHP's API Technology Department

A. Current Custodians

1. Peng Dong (#70). Peng Dong is currently the Deputy Director of Technology Department 1 within ZHP, which handles the product group dedicated to valsartan. He has worked for ZHP since 2006 and has been closely involved with the valsartan manufacturing process during his employment. He was a member of the committee that considered the manufacturing process change implemented in 2013, and was involved in the scale-up process validation. He is also involved with the equipment and raw materials, including recovered solvents, used in the valsartan API manufacturing process.

VII. ZHP's Regulatory Affairs Department

A. Current Custodians

1. Lihong (Linda) Lin (#93). Lihong Lin is the Director of API Regulatory Affairs. She has worked for ZHP since 1997. She oversees and coordinates regulatory submissions, including for valsartan to the FDA, and is involved with FDA inspections.
2. Yanfeng (Lucy) Liu (#96). Yanfeng Liu is the Deputy Director of API Regulatory Affairs. She has worked for ZHP since 2003 and reports to Lihong Lin. Yanfeng Liu oversees and coordinates regulatory submissions, including for valsartan to the FDA.
3. Ting (Ada) Zhou (#102). Ting Zhou is the Assistant Director of API Regulatory Affairs Group 1, one of the two groups that has handled valsartan. She has worked for ZHP since 2005 and was a member of the committee that considered the manufacturing process change for valsartan

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implemented in 2013. Before 2016, Ting Zhou handled regulatory submissions for valsartan, including to the FDA. Ting Zhou reports to Yanfeng Liu.

4. Ying Xiong (#38, #98). Ying Xiong is the Group Leader of API Regulatory Affairs Group 5, one of the two groups that has handled valsartan. She has worked for ZHP since 2010. Since 2016, Ying Xiong has handled regulatory submissions for valsartan, including to the FDA. Ying Xiong reports to Yanfeng Liu.

B. Custodians ZHP Opposes as Cumulative or Not Materially Involved with Valsartan

5. Feng E. Zhong (#39). Plaintiffs incorrectly identify Feng Zhong as an Associate Manager of Quality Research. As shown on the organizational charts, Feng Zhong is the Manager in charge of API Regulatory Affairs Group 2. As Mr. Jun Du explained to Plaintiffs on October 23, only Groups 1 and 5 have ever handled valsartan.
6. Danping Cai (#40). Plaintiffs incorrectly identify Danping Cai as an Assistant Director of Quality Research. As shown on the organizational charts, Danping Cai is the Assistant Director in charge of API Regulatory Affairs Group 3. As Mr. Jun Du explained to Plaintiffs on October 23, only Groups 1 and 5 have ever handled valsartan.
7. Yuanyan Chen (#41). Plaintiffs incorrectly identify Yuanyan Chen as a Supervisor of Quality Research. As shown on the organizational charts, Yuanyan Chen is the Group Leader in charge of API Regulatory Affairs Group 6. As Mr. Jun Du explained to Plaintiffs on October 23, only Groups 1 and 5 have ever handled valsartan.
8. Yueding Zhao (#106). Yueding Zhao is the Director of Finished Dose Regulatory Affairs for ZHP. Plaintiffs incorrectly indicate that ZHP proposed this custodian on October 23. In fact, the only discussion about Yueding Zhao occurred when Mr. Jun Du explained that ZHP's Finished Dose Regulatory Affairs division interacts only with Chinese agencies. All interactions with other regulatory agencies related to finished dose valsartan occur through ZHP's subsidiaries, *i.e.*, through Prinston for finished dose valsartan sold into the United States.
9. Jie Lin (#109). Jie Lin is currently the Assistant Manager of the API Patent Group within ZHP's Regulatory Affairs department. Although ZHP maintains patents related to valsartan, relevant documents responsive to

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Plaintiffs' patent-related requests can be identified through non-custodial files.

VIII. ZHP's API Sales Department

A. Current Custodians

1. Jie Wang (#116). Jie Wang is the current VP of API Sales. He has worked for ZHP since 2013, which is before any ANDA was approved that references ZHP's valsartan DMF. He oversees business development and API sales, including for valsartan.
2. Mi Xu (#120). Mi Xu is currently a Senior Director within the API Sales department. She reports to Jie Wang and has been employed by ZHP since 2007. She serves in several roles concurrently, including Market Development, European API Business, and Generics Key Account Business.
3. Sheng Zhong (#117). Sheng Zhong is currently a Director within the API Sales department. He reports to Jie Wang and has been employed by ZHP since 2018. He is responsible for business development with customers in India.
4. Hongchao Li (#119). Hongchao Li is currently a Manager within the API Sales department. He reports to Sheng Zhong and has been employed by ZHP since 2013, which is before any ANDA was approved that references ZHP's valsartan DMF. He handles accounts with customers in India.
5. Minda Cai (#115). Minda Cai is a former VP of API Sales who is recently deceased. He was employed by ZHP from 2002 until his death.

B. Proposed Custodians that ZHP Opposes as Cumulative or Not Materially Involved with Valsartan

The following three proposals are duplicative for the reasons identified below. We also note more generally that Plaintiffs have proposed that there be 13 custodians within the API Sales department, which is facially cumulative and overly burdensome.

6. Yihua Wang (#121). Yihua Wang was recently hired as a VP of API Sales to fill the position opened by Minda Cai's death. She was hired after the valsartan recall, has limited knowledge of the valsartan recall, and is duplicative of Jie Wang and Minda Cai.

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7. Fengyang Tang (#124) and Lina Wang (#125). These two employees are Assistant Managers who report directly to Mi Xu. They are duplicative of Mi Xu, and will likely only have cumulative documents that Mi Xu already possesses.

IX. ZHP's Finished Dose Custodians

A. Current Custodians

1. Minli Zhang (#34). Minli Zhang is the Director of Finished Dose Quality Assurance and Finished Dose Quality Control at the Xunqiao facility. She has worked for ZHP since 2001.
2. Xiaoming Liu (#66). Xiaoming Liu is currently the Director of Technology for Finished Dose. She has worked for ZHP since 2002.

B. Potential Additional Custodians

In light of the Court's recent ruling on the discoverability of certain topics related to valsartan finished dose, ZHP is endeavoring to collect organizational charts for the Xunqiao departments that handle activities related to quality assurance, quality control, production, and technology. ZHP will produce those organizational charts as soon as they are collected, and will propose its list of additional relevant custodians, if any, shortly thereafter.

X. Senior Management

The ZHP Defendants oppose the inclusion of both Jun Du (#1) and Baohua Chen (#2) as custodians. Jun Du is the Vice Chairman of ZHP's Board and the CEO of Prinston and Huahai U.S., and is not involved in the day-to-day management of valsartan production, testing, or root cause analysis. His high-level view of the manufacturing process and testing at issue in this case is not the quality of key information possessed by the custodians that the ZHP Defendants have already proposed. Furthermore, to the extent that the FDA has been addressing communications to Jun Du as the highest ranking individual who attended the 2018 Chuannan inspection, Prinston has and will continue to collect and produce those communications as required by the Court's order on core discovery. *See* Dkt. 88.⁵ As for Baohua Chen, he is the President of ZHP. ZHP is a large pharmaceutical company with thousands of employees. As a high ranking executive, Mr. Chen is far removed from the day-to-day production process for valsartan, and a search of his custodial file is unlikely to reveal any materially relevant documents. Those documents are found in the files of the ZHP employees we have proposed to Plaintiffs as the most appropriate custodians

⁵ In addition, Prinston will produce internal communications involving Mr. Du regarding the alleged contamination of valsartan, the U.S. recall, and the FDA's investigation.

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directly responsible for the manufacture, testing, quality assurance, and sale of the company's valsartan products.

XI. Solco Healthcare U.S., LLC Custodians

As previously explained in various meet and confers and filings to the Court, Solco is the United States distributor of ZHP's finished dose products, including valsartan.

A. Current Custodians

1. Hai Wang (#133). Hai Wang is the President of Solco. He has worked for the ZHP companies since 2005 and was transferred to Solco in January 2017. He is responsible for overseeing all sales operations at Solco, including for valsartan.
2. Chris Keith (#131). Chris Keith is the Senior VP of Sales at Solco. He started working for Prinston in 2014 and was transferred to Solco in 2017. He reports to Hai Wang and is responsible for pricing, including for valsartan.

B. Custodians Solco Agrees to Add

3. David Ayres (#135). David Ayres is currently the VP of Sales at Solco. He reports to Hai Wang and is responsible for sales, including for valsartan.

C. Proposed Custodians Solco Opposes as Cumulative or Not Materially Involved with Valsartan

4. Matthew Arnold (#138). Matthew Arnold is a former Account Manager within the Sales department at Solco. He reported to Hai Wang and would have cumulative information to Mr. Wang and to David Ayres. To the extent Plaintiffs' justification for including Mr. Arnold is that he authored the Solco customer list produced during core discovery, such spreadsheet documents can be collected from non-custodial files.

XII. Prinston Pharmaceutical Inc. Custodians

As previously explained in various meet and confers and filings to the Court, Prinston is the FDA Liaison for ZHP and the holder of the two valsartan ANDAs.

A. Current Custodians

1. Xiaodi Guo (#100). Xiaodi Guo is the Senior VP of Research & Development for Prinston. He has worked for the ZHP companies since

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2005 and was transferred from Huahai U.S. to Prinston. He is in charge of research and development operations for finished dose products, including valsartan.

2. Lijie Wang (#97). Lijie Wang is the VP of Regulatory Affairs for Prinston. Lijie Wang has worked for Prinston since 2017 and reports to Xiaodi Guo. Lijie Wang has communicated with the FDA related to valsartan and related to the recalls.
3. Remonda Gergis (#17). Remonda Gergis is currently the VP of Quality Assurance for Prinston. She has worked for Prinston since 2016. She is responsible for quality assurance related to valsartan.

B. Proposed Custodians Prinston Opposes as Cumulative or Minimally Involved with Valsartan

4. Minfa Wang (#5). Minfa Wang is the VP of the Analytical Lab at Prinston. She has not been involved with valsartan or with the recalls. She attended an FDA meeting related to the valsartan recall, but only as a stand-in for Qiangming Li, who was unable to attend on ZHP's behalf.
5. Jack Guan (#9). Jack Guan reports to Minfa Wang within Prinston's Analytical Lab. Like Minfa, Jack has not been involved with valsartan.
6. Wei (Helena) Tong (#101). Wei Tong is a former Director of Regulatory Affairs for Prinston. She reported to Xiaodi Guo. She left Prinston in early 2017, before the recalls.
7. Louis Zhao (#103). Louis Zhao is an employee within the Regulatory Affairs department at Prinston. He started working for Prinston in 2018. He has not been involved with valsartan.
8. Guangyu (Erin) Luo (#104). Guangyu Luo is currently a Manager within Prinston's Regulatory Affairs department. She reports to Lijie Wang and is cumulative to that custodian.
9. Jingran (Jenny) Lu (#105). Jingran Lu is currently a Senior Associate within Prinston's Regulatory Affairs department. She reports to Lijie Wang and is cumulative to that custodian.
10. Xin (Will) He (#136). Xin He is currently a Manager within Prinston's Research and Development group. He has not been involved with valsartan.

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11. Peng Shang (#137). Peng Shang is a Senior Associate within Prinston's Business Development group. The Solco sales custodians have superior information related to valsartan sales.
12. Lesley Zhu (#132). Lesley Zhu is currently the Senior VP of Business Development at Prinston. The Solco sales custodians have superior information related to valsartan sales.
13. Min (Michelle) Hu (#134). Min Hu is currently a Senior Director within the Business Development group at Prinston. The Solco sales custodians have superior information related to valsartan sales.
14. Eric Wen-Chien Tsai (#80). Eric is an employee of Prinbury Biopharm, not Prinston.

XIII. Huahai U.S., LLC Custodians

As previously explained in various meet and confers and filings to the Court, Huahai U.S. is the United States distributor for ZHP's API.

A. Current Custodians

Huahai U.S. had not proposed or agreed to any custodians before this date because it has not sold any valsartan API to United States customers for commercial use.

B. Custodians Huahai U.S. Agrees to Add

1. John Iozzia (#130). John Iozzia is the Director of Sales for Huahai U.S. He has been responsible for the sale of research samples of valsartan API to U.S.-based customers.

C. Custodians Huahai U.S. Opposes as Not Materially Involved with Valsartan

2. Xin Geng (#8). Xin Geng is a research scientist for Huahai U.S. He has not worked on valsartan.
3. Zhi Chen (#95). Zhi Chen is a former Huahai U.S. employee who left in 2016.
4. Qun (Kathy) Zhang (#99). Qun Zhang is a former Huahai U.S. employee who left in 2015.

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XIV. Request for Additional Information

We request additional information about the following custodians, whom we have been unable to identify through searches of core discovery or through investigation with our clients.

1. Qing Wang (#6), about whom Plaintiffs have provided no information except a reference to their October 8, 2019 communication about custodians. A Qing Wang does not appear in the list that Plaintiffs shared on October 8.
2. Min Xang (#113). Plaintiffs indicate that Defendants proposed Min Xang on October 16, 2019. Our records show no reference to a Min Xang.
3. Wei Tian (#147), about whom Plaintiffs' only proffer is "Prinbury website."

XV. Shanghai Syncros and Prinbury Biopharm

Plaintiffs have proposed four employees of Shanghai Syncros (#7, #139–141) and 14 employees of Prinbury Biopharm (#142–155) as ESI custodians. As Jun Du explained to Plaintiffs on October 23, Shanghai Syncros and Prinbury Biopharm are subsidiaries of ZHP. Plaintiffs have not named these entities as defendants, or served them with process or with any document requests. Furthermore, the only justification that Plaintiffs proffer for most of these custodians is "Linkedin" or "Prinbury website," without any additional information and without any reason to believe that those custodians had any involvement with valsartan. Nevertheless, ZHP is currently determining whether it has authority to collect custodial files from employees of these companies, and which, of any of these employees, have had meaningful involvement with valsartan to warrant their being identified as ESI custodians.

XVI. Third-Party Consultants

Plaintiffs have named five third-party consultants as proposed custodians (#21 and #156–159). None of these consultants are employees of ZHP, and none have ZHP email accounts. As such, ZHP does not have the authority to collect and search their entire email accounts. In addition, Plaintiffs will receive relevant communications between the ZHP Defendants and these consultants through searches of the agreed-upon custodial files of actual employees. Nevertheless, the ZHP Defendants are currently determining the full scope of documents they are entitled to request from these consultants under the applicable contracts.

* * *

As is evident from the above, we have already incurred significant time, expense, and burden evaluating Plaintiffs' incredibly overbroad proposed custodian list, which burden has been compounded by Plaintiffs' belated identification of dozens of custodians. In addition to our proposed custodians, we have identified 7 custodians from Plaintiffs' list that are appropriate

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additions, bringing the current total to 35. While we believe that the 35 custodians currently proposed to be more than sufficient given their substantive involvement in all aspects of valsartan process development, production, testing, quality assurance, and regulatory affairs, I re-emphasize my hope that you will use the information in this letter to significantly reduce Plaintiffs' list of proposed custodians to 50 as I proposed on Monday's call, as that number cannot be reasonably disputed as adequate. Please let me know as soon as possible whether Plaintiffs will agree to this reasonable proposal. If so, then we can turn our efforts away from briefing and towards developing the final list of 50 custodians.

Sincerely,

/s/ Seth A. Goldberg

SAG
Encl.

cc: valpec@kirtlandpackard.com
Jessica Priselac (jpriselac@duanemorris.com)
Lori G. Cohen (cohenl@gtlaw.com)
Clem C. Trischler (cct@pietragallo.com)
Jessica M. Heinz (Jheinz@c-wlaw.com)
Janet L. Poletto (jpoletto@hkmpp.com)
Alexia Brancato (alexia.brancato@kirkland.com)

| Plaintiffs' Preliminary List of Custodians for ZHP and Its Subsidiaries as of 11/25/2019 - with Numbers | | | | | | | |
|---|------------|-----------|---|-----------------------------------|---------------------|----------------|---|
| # | First name | Last name | Title | Department | Co. | Proffered by | Explanation |
| Senior Management | | | | | | | |
| 1 | Jun | Du | Vice President of ZHP, CEO of Huahai US, Prinston, Solco, and PrinJohnson | | | See Title Cell | P - 10.8.19 |
| 2 | Baohua | Chen | Chairman and General Manager | | ZHP and PrinJohnson | | P - 11.12.19 |
| Analytical | | | | | | | |
| 3 | Xie | Chaojun | | Analyst | ZHP | P - 10.8.19 | |
| 4 | Min | Li | VP | Analytical Operations | ZHP | D - 9.23.19 | |
| 5 | Minfa | Wang | VP | Analytical Operations | ZHP/Prinston | P - 10.8.19 | |
| 6 | Qing | Wang | | | ZHP | P - 10.8.19 | |
| 7 | Dachuan | Zhao | VP | Analytical, Shanghai R&D Center | ZHP | P - 11.12.19 | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| 8 | Xin | Geng | Post Doctoral Fellow and Research Scientist | | Huahai US | P - 11.12.19 | "Expertise in various purification techniques including chromatography, recrystallization, and distillation" -Linkedin |
| 9 | Jack | Guan | Senior Director Analytical Operations | | Prinston | P - 11.12.19 | "A pharmaceutical professional with strong expertise in analytical R&D, Quality Control, Pre- formulation, Quality Assurance, Compliance and Regulatory Affairs. Proven track records of leading operations and activities in analytical R&D, quality units, health authority inspections, and project management." -Linkedin |
| 10 | XiaXia | Zhang | Analytical and Testing Department Manager | Chuannan Branch Analytical Center | ZHP | P - 11.22.19 | Org Chart |
| 11 | Jun | Wang | Finished Dose Gase Stage Team | Chuannan Branch Analytical Center | ZHP | P - 11.22.19 | Org Chart |
| 12 | Chun | Yang | Finished Dose Liquid Phase Team | Chuannan Branch Analytical Center | ZHP | P - 11.22.19 | Org Chart |
| 13 | Guang | Zheng | Raw Material Central Control Instrument Team | Chuannan Branch Analytical Center | ZHP | P - 11.22.19 | Org Chart |

| | | | | | | | |
|----------------|-----------|---------|--|--|------------------|--------------|--|
| 14 | XianLiang | Zhang | Raw Material Central Control Physico-Chemical Team | Chuannan Branch Analytical Center | ZHP | P - 11.22.19 | Org Chart |
| 15 | Yun | Jin | | Chuannan Branch Analytical Center | ZHP | P - 11.22.19 | Org Chart |
| Quality | | | | | | | |
| 16 | Wei | Cheng | VP | API Quality Assurance | ZHP | P - 10.8.19 | |
| 17 | Remonda | Gergis | VP | Quality Assurance | Prinston | P - 10.8.19 | |
| 18 | Zheng | Youqing | Deputy Manager | Quality Assurance | ZHP | P - 10.8.19 | |
| 19 | Jucai | Ge | Director | Quality Assurance (API Division) | ZHP | D - 9.23.19 | |
| 20 | Yuelin | Hu | Assistant Director | Quality Assurance (API Division) | ZHP | D - 10.7.19 | |
| 21 | Ziqiang | Gu | Independent Consultant | | ZHP and Prinston | P - 10.8.19 | |
| 22 | Xiaohong | Zhao | Director | Quality Assurance (Chuannan Site) | ZHP | P - 10.8.19 | |
| 23 | Hongliang | Wang | | Quality | ZHP | P - 11.12.19 | Prepared Method Validation Report of Valsartan PRINSTON00031401 |
| 24 | Zhen | Ye | | Quality | ZHP | P - 11.12.19 | Reviewed part of Method Validation Report of Valsartan PRINSTON00031402 |
| 25 | Baozhen | Chen | Director | Corporate Quality Assurance | ZHP | P - 11.12.19 | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| 26 | Cunxiao | Ye | Vice President | Quality Assurance, Headquarters | ZHP | P - 11.12.19 | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| 27 | Caifeng | Zhao | Manager | Quality Assurance | ZHP | P - 11.12.19 | Prepared Deviation Investigation Report of Valsartan TEA Process V1, 2, & 3 PRINSTON0073443, 0075797, 0076100 |
| 28 | Dongqin | Wang | Assistant Director | Quality Assurance at Chuannan Site East Zone | ZHP | P - 11.12.19 | Reviewed and signed off on Deviation Investigation Report of Valsartan TEA Process V1, 2, & 3 PRINSTON0073443, 0075797, 0076100; attended 5.19.17 meeting after the FDA inspection PRINSTON0074159 |
| 29 | Zhizhang | Ding | Assistant Manager | Formulation Quality Assurance | ZHP | P - 11.12.19 | Reviewed and approved Elemental Impurity Risk Assessment Report for Valsartan Tablets PRINSTON00036384 |

| | | | | | | | |
|----|-----------|-----------|------------------------------|---|-----|---|--|
| | | | | | | | Reviewed and approved Validation Report of LC-MS Method for NDBA in Losartan Potassium PRINSTON0074642; ; reviewed and approved the Validation Report of LC-MS Method for NMBA in Irbesartan PRINSTON0074712 |
| 30 | Y.F. | Chen | Senior Supervisor | API Quality Assurance | ZHP | P - 11.12.19 | |
| 31 | Xiong | Fei | Analyst | Quality Control | ZHP | P - 10.8.19 | |
| 32 | Hu | Guangping | Director | Quality Control | ZHP | P - 10.8.19 | |
| 33 | Huang | Rui | Director | Quality Control | ZHP | P - 10.8.19 | |
| 34 | Minli | Zhang | Director | Finished Dose Quality Assurance and Quality Control | ZHP | D - 10.16.19 | |
| 35 | Qiangming | Li | Director | Quality Control (API Division) | ZHP | D - 9.23.19 | |
| 36 | Zie | Chaojun | Analyst | Quality Control | ZHP | P - 10.8.19 | |
| 37 | Quang | Zhou | Analyst | Quality Research | ZHP | D - 10.23.19 | |
| 38 | Ying | Xiong | Supervisor | Quality Research | ZHP | D - 10.23.19 | |
| 39 | Fong E. | Zhuong | Associate Manager | Quality Research | ZHP | Discussed but not agreed to on 10.23.19 | Org Chart |
| 40 | Dan Ping | Cai | Technical Assistant Director | Quality Research | ZHP | Discussed but not agreed to on 10.23.19 | Org Chart |
| 41 | Yuanyan | Chen | Supervisor | Quality Research | ZHP | Discussed but not agreed to on 10.23.19 | Org Chart |
| 42 | Yinhua | Tang | Assistant Director/Manager | Quality Control | ZHP | P - 11.12.19 | Reviewed and signed off on Deviation Investigation Reports of Valsartan TEA Process PRINSTON0073443, etc.; attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| 43 | Fei | Shang | QP | Quality VP | ZHP | P - 11.12.19 | Reviewed and approved the third version of the Deviation Investigation into the TEA process PRINSTON0076100 |
| 44 | Yun | Jin | Supervisor | Chuannan Quality Control | ZHP | P - 11.12.19 | Drafted Assay Method Validation Report for Valsartan (Supplement) PRINSTON00009948; draft Chiral Purity Analytical Method Validation Protocol for TDCI Compound PRINSTON00077405 |
| 45 | Tian | Zhang | Analyst | Chuannan Q Control | ZHP | P - 11.12.19 | Reviewed and signed off on Assay Method Validation Report for Valsartan (Supplement) PRINSTON00009948; reviewed and signed off on Chiral Purity Analytical Method Validation Protocol for TDCI Compound PRINSTON00077405 |

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|----|----------|-------|-------------------|-----------------------------|-----|--------------|--|
| 46 | Xianhua | Zhang | Deputy Director | Chuannan Quality Control | ZHP | P - 11.12.19 | Reviewed and signed off on Assay Method Validation Report for Valsartan (Supplement) PRINSTON00009948; reviewed and signed off on Chiral Purity Analytical Method Validation Protocol for TDCI Compound PRINSTON00077405 |
| 47 | Yuping | Chen | Deputy Manager | Formulation Quality Control | ZHP | P - 11.12.19 | Author of Elemental Impurity Risk Assessment Report for Valsartan Tablets PRINSTON00036384 |
| 48 | Xiaoling | Li | Manager | Formulation Quality Control | ZHP | P - 11.12.19 | Reviewed and signed off on Elemental Impurity Risk Assessment Report for Valsartan Tablets PRINSTON00036384 |
| 49 | Qiang | Zhuo | Analyst | API Quality Research | ZHP | P - 11.12.19 | Drafted Validation Report of GC- MS Method for Detection of NDMA in Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326 |
| 50 | Tong | Wu | Analyst | API Quality Research | ZHP | P - 11.12.19 | Drafted Validation Report of GC- MS Method for Detection of NDMA in Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326 |
| 51 | Tan | Xiao | Senior Supervisor | API Quality Research | ZHP | P - 11.12.19 | Drafted Validation Report of GC- MS Method for Detection of NDMA in Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326; reviewed and approved Validation report of the LC-MS method for NDBA in Losartan Potassium PRINSTON0074642; reviewed and approved the Validation Report of LC-MS Method for NMBA in Irbesartan PRINSTON0074712 |
| 52 | Wenbin | Chen | Analysis Director | API Quality Research | ZHP | P - 11.12.19 | Reviewed and signed off on Report of GC-MS Method for Detection of NDMA in Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326; ; reviewed and approved the Validation Report of LC-MS Method for NMBA in Irbesartan PRINSTON0074712 |
| 53 | Nan | Tong | Senior Supervisor | API Quality Research | ZHP | P - 11.12.19 | Approved the cGMP compliance for its intended use of Report of GC-MS Method for Detection of NDMA in Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326 |

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|----|-----------|--------|--|---------------------------------------|-----|--------------|---|
| | | | | | | | Reviewed data in Hydrochlorothiazide Residual Solvent Method Validation Report PRINSTON00064288; Reviewed Comparison of Valsartan USP Method and In-house Method for Integrity and Correctness PRINSTON00064389 |
| 54 | Wenping | Hu | Team Leader | Quality Research | ZHP | P - 11.12.19 | |
| 55 | Wenquan | Zhu | Director | API Quality Research | ZHP | D- 10.16.19 | |
| 56 | X. G. | Liu | Quality Researcher | API Quality Research | ZHP | P - 11.12.19 | Drafted Validation report of the LC MS method for NDBA in Losartan Potassium PRINSTON0074642 |
| 57 | Y.Y. | He | Quality Researcher | API Quality Research | ZHP | P - 11.12.19 | Drafted Validation Report of LC- MS Method for NMBA in Irbesartan PRINSTON0074712 |
| 58 | Ye | Jenson | | QP | ZHP | P - 11.12.19 | Approved the Deviation Investigation Reports of Valsartan TEA Process PRINSTON0073443, etc. |
| 59 | Jieyun | Wang | Director | Quality Assurance | ZHP | P - 11.22.19 | PRINSTON00077850 |
| 60 | Ting | Sung | Manager | Quality Control | ZHP | P - 11.22.19 | Org Chart |
| 61 | Jian | Ye | Deputy Manager, Group I | Quality Control | ZHP | P - 11.22.19 | Org Chart |
| 62 | Houming | Zhou | General Detection, Tachnical Deputy Director | API Quality Study/Research Department | ZHP | P - 11.22.19 | Org Chart |
| 63 | Xiao | Yu | Associate Director | API Quality Study/Research Department | ZHP | P - 11.22.19 | Org Chart |
| 64 | Yang | Han | Supervisor | Quality Research | ZHP | P - 11.22.19 | Org Chart |
| 65 | Chaohua | Bao | Supervisor | API QR | ZHP | P - 11.22.19 | Prepared Comparison of Valsartan USP Method and In-house Method PRINSTON00064389 |
| | | | Manufacturing | | | | |
| 66 | Xiamong | Liu | Head | Technical for Finished Dose | ZHP | D - 10.16.19 | |
| 67 | Congsheng | Jin | Valsartan Workshop Director | | ZHP | P - 11.12.19 | Identified as the person "responsible for production of Valsartan" |
| 68 | Yongjun | Jin | Factor Assistant Director | | | | Described as a "professional engineer," and "has a wide experience at production technology management and is responsible for the technological development of all bulk drugs" |
| 69 | Dong | Peng | Director | Technical Department | ZHP | D - 9.23.19 | |
| 70 | Peng | Wang | Senior Director | API Manufacturing | ZHP | D - 9.23.19 | |
| 71 | Youhu | Wang | Technology Leader | | ZHP | P - 11.12.19 | "Is responsible for Valsartan" |

| | | | | | | | |
|----|----------------|------------|------------------------------------|---|--------------|--------------|---|
| 72 | Jiangzhong | Yu | API and Intermediate Plant Manager | Manufacturing | ZHP | P - 11.12.19 | Responsible for all bulk drugs (including intermediates) at ZHP |
| 73 | Wenling | Zhang | Director Assistant | Technical, API Chuannan site West Zone (counterpart to Peng Dong) | ZHP | P - 11.12.19 | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| 74 | Lijin | Jiang | VP | API Operation/Facility Director, API Chuannan Site | ZHP | P - 11.12.19 | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| 75 | Zhengjun | Jia | Deputy Plant Director | Engineering and Maintenance, API Chuannan site East Zone | ZHP | P - 11.12.19 | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| 76 | Junhui | Zuo | Deputy Plant Director | Engineering and Maintenance, API Chuannan site West Zone | ZHP | P - 11.12.19 | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| 77 | Wei | Chen | Deputy Director | Production Department | ZHP | P - 11.12.19 | Reviewed and approved Deviation Investigation Reports regarding the TEA Process PRINSTON0073443, 0075797, 0076100 |
| 78 | Lina | Wu | Senior Supervisor | Formulation Technology at ZHP | ZHP | P - 11.12.19 | Author of Elemental Impurity Risk Assessment Report for Valsartan Tablets PRINSTON00036384 |
| 79 | Xiaoming | Liu | Director | Formulation Technology at ZHP | ZHP | P - 11.12.19 | Reviewed and signed off on Elemental Impurity Risk Assessment Report for Valsartan Tablets PRINSTON00036384 |
| 80 | Eric Wen-Chien | Tsai, PhD | General Manager | Prinston and Prinbury BioPharm | P - 11.12.19 | | Authorized signatory and sponsor or Quality Assurance Authentication of Valsartan. PRINSTON00029811. "Eric joined Prinbury BioPharm as General Manager in 2009, wholly owned subsidiary of Prinston, a Research and Development center located in Shanghai China. In this role he leads the R&D efforts has been making significant contribution to Prinston pipeline growth. Eric came to the company with strong technical expertise and management skills." - Prinston Website |
| 81 | Pieter | Groenewoud | Executive Director | Technology | ZHP | P - 11.12.19 | Reviewed Master Packaging Record Approval PRINSTON00021688 |
| 82 | Chunmin | Xu | Vice President | | ZHP | P - 11.22.19 | PRINSTON00070584, 79392 |
| 83 | Hu | Zhou | Factory Director | | ZHP | P - 11.22.19 | PRINSTON00070586 |
| 84 | Ruqi | Zhou | Factory Assistant Director | | ZHP | P - 11.22.19 | PRINSTON00070587, 79392 |
| 85 | Kaai | Yang | Technical Manager | | ZHP | P - 11.22.19 | PRINSTON00070587, 79392 |

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|-------------------|-----------------|----------|-----------------------------|-----------------------------------|---|---|--|
| 86 | Ruping | Ren | Auxiliary Workshop Director | | ZHP | P - 11.22.19 | PRINSTON00077851 |
| 87 | Meng | Yanhua | General Manager | Chuannan Product Technical Center | ZHP | P - 11.22.19 | Org Chart |
| 88 | Yan | Fengfeng | Director of Tech | Chuannan Product Technical Center | ZHP | P - 11.22.19 | Org Chart |
| 89 | Liang | Zunjun | Associate Director | Chuannan Product Technical Center | ZHP | P - 11.22.19 | Org Chart |
| 90 | Hu | Zhichen | Manager | Chuannan Product Technical Center | ZHP | P - 11.22.19 | Org Chart |
| 91 | Zhan | Xiauhui | "(Valsartan)" | Chuannan Product Technical Center | ZHP | P - 11.22.19 | Org Chart |
| 92 | Xie | Mengmeng | General Supporting Group | Chuannan Product Technical Center | ZHP | P - 11.22.19 | Org Chart |
| Regulatory | | | | | | | |
| 93 | Linhong (Linda) | Lin | Director | Regulatory Affairs Department | ZHP | D - 9.23.19 | |
| 94 | Wei | Chen | Translator | | ZHP | P - 11.12.19 | Translatered 08/26/2018 Ltr to the FDA |
| 95 | Zhi | Chen | | | Huahai US | P - 10.8.19 | |
| 96 | Yanfeng (Lucy) | Liu | Deputy Director / Manager | Regulatory Affairs | ZHP | D - 10.7.19 | |
| 97 | Lije | Wang | VP | Head of Regulatory Affairs | Prinston | P - 10.8.19 | |
| 98 | Ying | Xiong | Supervisor | Regulatory Affairs | ZHP | D 10.16.19 | |
| 99 | Quo (Kathy) | Zhang | Senior Manager | Regulatory Affairs | Huahai US | P - 10.8.19 | |
| 100 | Xiaodi | Guo | Vice President | | Huahai US (linkedin), Prinston (website), and Solco (affidavits of service) | P for Prinston/Huahai US - 10.8.19 / Solco - 11.12.19 | He has accepted service as Solco's VP. |
| 101 | Wei (Helen) | Tong | Director | Regulatory Affairs | ZHP and Prinston? | P - 11.12.19 | Listed on ANDA Documents |
| 102 | Ting (Ada) | Zhou | Assistant Director | Regulatory Affairs | ZHP | D - 10.7.19 | |
| 103 | Louis | Zhao | | Regulatory Affairs | Prinston | P - 11.12.19 | Linkedin |

| | | | | | | | | |
|-----|----------|----------|---|---------------------------------|--------------|--------------|--|--|
| | | | Associate (2013-2015), Senior Associate (2015-2016), Specialist (2016-2017), Manager (2017-Present) | | | | "Regulatory Affairs, mainly on regulatory submissions (from draft to e-CTD compilation), pharmacovigilance (AE handling and submission) and generic labeling (content, artwork and SPL)." - Linkedin | |
| 104 | Guangyu | Luo | | Prinston | P - 11.12.19 | | | |
| 105 | Jenny | Lu | Senior Associate | Regulatory Affairs | Prinston | P - 11.12.19 | Linkedin | |
| 106 | Yuding | Zhao | Director | Finished Dose RA | ZHP | D - 10.23.19 | | |
| 107 | Yiming | Tang | | | | P - 11.22.19 | Contact Person for ZHP's U.S. Agent PRINSTON0076915 | |
| 108 | Sun | Dengxue | Manager | API R&D, Regulation Affairs | ZHP | P - 11.22.19 | Org Chart | |
| 109 | Lin | Jie | Deputy Manager | API Patent, Regulation Affairs | ZHP | P - 11.22.19 | Org Chart | |
| | | | | Procurement | | | | |
| 110 | Min | Hu | | Purchasing | ZHP | D - 10.16.19 | | |
| 111 | Weiwei | Xu | | Purchasing | ZHP | D - 10.16.19 | | |
| 112 | Min | Xu | | Purchasing | ZHP | D - 10.16.19 | | |
| 113 | Min | Xang | | Procurement | ZHP | D - 10.16.19 | | |
| 114 | Zheng | Gaozhe | | Purchasing | ZHP | D - 10.16.19 | Was a person who was responsible for procuring solvents | |
| | | | | API Sales | | | | |
| 115 | Minda | Cai | Former VP | API Sales | ZHP | D - 10.16.19 | | |
| 116 | Jie | Wang | VP | Business Development | ZHP | D - 9.23.19 | | |
| 117 | Sheng | Zhong | Director | Business Development | ZHP | D - 10.16.19 | | |
| 118 | Wei | Chang | Translator | Business Development, API Sales | ZHP | D - 10.23.19 | | |
| 119 | Hongchao | Li | Manager | Business Development | ZHP | D - 10.16.19 | | |
| 120 | Xu | Mi | | Business Development, API Sales | ZHP | D - 10.16.19 | | |
| 121 | Wang | Yihua | Vice President | Sales | ZHP | P - 11.22.19 | Org Chart | |
| 122 | Ki | Qing | "Brand Customer" | Sales | ZHP | P - 11.22.19 | Org Chart | |
| 123 | Tong | Zengyuan | "Customer Service" | Sales | ZHP | P - 11.22.19 | Org Chart | |
| 124 | Tang | Fengyang | Manager Assistant | Sales | ZHP | P - 11.25.19 | Org Chart | |
| 125 | Wang | Lina | Manager Assistant | Sales | ZHP | P - 11.25.19 | Org Chart | |
| 126 | Li | Qing | Director of Original Drug, Key Account Business Department | Sales | ZHP | P - 11.25.19 | Org Chart | |
| 127 | Xu | Baoxi | Director Assistant | Sales | ZHP | P - 11.25.19 | Org Chart | |
| 128 | Wu | Yuehua | Manager of Document Group | Sales | ZHP | P - 11.25.19 | Org Chart | |

| | | | | | | | |
|-------------------------------|-------------|--------|---|------------------------|---|--|--|
| 129 | Wang | Haiqun | Assistant Manager of Office Work Group | Sales | ZHP | P - 11.25.19 | Org Chart |
| Other Sales | | | | | | | |
| 130 | John | Iozzia | Director | Sales | Huahai US | D - 10.16.19 | |
| 131 | Chris | Keith | Director | Sales | Solco/Prinston at some point as VP | D - 10.22.19 for Solco / Prinston - 11.12.19 | Solco's Website |
| 132 | Lesley | Zhu | SVP, Business Development & Portfolio | Sales | Prinston | P - 10.8.19 | |
| 133 | Hai | Wang | VP, President, President | | Huahai US (linkedin), Prinston (website), & Solco (website), respectively | P for Solco - 10.8.19 | |
| 134 | Min | Hu | Manager of Business Development and Senior Director of Business Development | | Huahai US (2007-2012) and Prinston (2012-Present), respectively | P - 11.12.19 | Linkedin |
| 135 | David | Ayres | Vice President | Sales | Solco | P - 11.12.19 | Solco's Website |
| 136 | Xin (Will) | He | Scientist (2012-2016), Manager (2019-Present) | | Prinston | P - 11.12.19 | "Working at formulation position of Product Development Department." -Linkedin |
| 137 | Peng | Shang | Senior Associate of Business Development/Supply Chain | | Prinston | P - 11.12.19 | Linkedin |
| 138 | Matthew | Arnold | National Account Manager from 2016-2019 | | Solco | P - 11.12.19 | Linkedin and Author of Only Solco-stamped document |
| Syncores | | | | | | | |
| 139 | Eric | Gu | Manager | | Shanghai Syncores | P - 10.8.19 | |
| 140 | James (Jun) | Wen | President | | Shanghai Syncores | P - 11.12.19 | Linkedin |
| 141 | Frank | Zhao | VP | | Shanghai Syncores | P - 11.12.19 | Linkedin |
| Prinbury BioPharm Ltd. | | | | | | | |
| 142 | Wenjian | Cai | General Manager | | Prinbury | P - 11.12.19 | Prinbury website |
| 143 | Dachuan | Zhao | Executive Deputy General Manager | | Prinbury | P - 11.12.19 | Prinbury website |
| 144 | Ping | Wen | Executive Director | | Prinbury | P - 11.12.19 | Prinbury website |
| 145 | Yuanyuan | Xie | Director | Pharmaceutical Affairs | Prinbury | P - 11.12.19 | Prinbury website |
| 146 | Li | Tan | Director | Project Management | Prinbury | P - 11.12.19 | Prinbury website |

| | | | | | | |
|--------------------|----------|------------|--|---|--------------|--|
| 147 | Wei | Tian | Deputy General Manager of Analysis and Research | Prinbury | P - 11.12.19 | Prinbury website |
| 148 | Hongchun | Qiu | Deputy General Manager of Pharmaceutical Preparation Product Development | Prinbury | P - 11.12.19 | Prinbury website |
| 149 | Shine | Chen | Scientist | Prinbury | P - 11.12.19 | Prepared Method Verification Report for Valsartan PRINSTON00039715 |
| 150 | Tina | Liu | Senior Scientist | Prinbury | P - 11.12.19 | Reviewed Method Verification Report for Valsartan PRINSTON00039715 |
| 151 | Yun | Tian | Senior Director | Prinbury | P - 11.12.19 | Approved Method Verification Report for Valsartan PRINSTON00039715 |
| 152 | Lily | Tan | QA Manager | Prinbury | P - 11.12.19 | Approved Method Verification Report for Valsartan PRINSTON00039715 |
| 153 | Alex | Liu | Scientist | Prinbury | P - 11.12.19 | Prepared Dissolution Comparison Study Report of Valsartan PRINSTON00050114 |
| 154 | Ashley | Lin | Associate Scientist | Prinbury | P - 11.12.19 | Prepared Method Robustness Study Report for Valsartan PRINSTON0039541 |
| 155 | Yula | Wang | Executive Director | Prinbury | P - 11.12.19 | Reviewed and approved Master Production Batch Record Approval PRINSTON00064070 |
| Consultants | | | | | | |
| 156 | Derek | Zhang, PhD | | Alavanda Regulatory & Drug Development Consulting, Inc. (Regulatory Consultant for Princeton Pharmaceutical Inc.) | D - 10.23.19 | |
| 157 | Dylan | Yao, Ph.D. | Chief Scientific Officer & Senior Vice President | Jonn Laboratories Inc. (Consultant for Princeton Pharmaceutical Inc.) | D - 10.23.19 | |
| 158 | Charles | Wang | VP of Drug Safety and DMPK | Consultant from InnoCare Pharma, Inc. for ZHP | D 10.23.19 | |
| 159 | Douglas | Campbell | Consultant | ZHP | P - 11.22.19 | Email PRINSTON00070408 |